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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,501	03/19/2001	Prem S. Paul	201503US55XD	1105

7590 08/09/2002

Sharon E. Crane, Ph.D.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	16

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,501	PAUL ET AL.	
	Examin r	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 32-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9,12,15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group V, claims 30 and 31, in Paper No. 14 is acknowledged. The traversal is on the ground(s) that Group I, with claims drawn to DNA, has not been distinguished from Group V, drawn to kits/DNA methods; that Group III, directed to antibodies and vaccines, has not been distinguished from Group IV, directed to antibodies, kits, and detection method; that the peptides of Group II are encoded by the DNA of Group I; that the virus of Group VI contains both polynucleotides and peptides; that the polynucleotide of Group I encompasses RNA as well as DNA, so the reasons given for requiring restriction are not accurate; that no evidence has been provided to support the assertions of differences in structures and properties between classes of invention. These arguments have not been found persuasive because the polynucleic acid recited in the claims of Group I, which Applicant has correctly pointed can encompass RNA as well as DNA, encodes a polypeptide, while the polynucleotides recited in Group V are disclosed only as "primers" of 10-50 nucleotides in length and are intended for use in detection methods involving amplification. Clearly inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being used together and have different modes of operation, functions, and effects as claimed. With respect to Groups III and IV, the antibody product claims were placed in both groups, to be examined together with one method of use, should either group have been elected. The methods of use are distinct, unrelated methods having different

modes of operation, functions and effects, and the antibody diagnostic kits are not used in methods of treatment. The polynucleic acids, proteins, and viruses are different products as previously discussed, and have different classifications, as do the other claim groups, each requiring a separate search. With respect to Applicant's statement that no evidence has been provided to support the assertions of differences in structures and properties, while examiners must provide reasons and/or examples to support restriction requirements, citation of documents is not generally required (see MPEP 803).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-29 and 32-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Claims 30 and 31 are under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is unclear insofar as it recites "a polynucleotide having a sequence of from 10 to 50 nucleotides in length which hybridizes to a genomic polynucleotide from an Iowa strain of porcine reproductive and respiratory syndrome virus." First, Applicant

is requested to clarify the metes and bounds intended by "an Iowa strain of porcine reproductive and respiratory syndrome virus" since it appears from the disclosure at page 24 that "Iowa strain" excludes, e.g., VR 2332; strains found in Canada; or strains found in Europe, including Lelystad; however, it remains rather unclear what viral characteristics are required in order to be included in "an Iowa strain," particularly since it is clear from Figs. 8, 10, 17, 18, 21, e.g., of the instant specification that there are several stretches of at least 10 nucleotides within the sequence of the Lelystad virus that are identical to corresponding sequences within viruses disclosed as being "Iowa strain" viruses, making it unclear what polynucleotide or polynucleotide composition Applicant intends to claim.

Since claims 30 and 31 recite features not disclosed in parent application 08/131625 or in 07/969071, they receive the effective filing date of 08/301,435, i.e., September 1, 1994.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort et al., WO92/21375, published December 10, 1992, and cited by Applicant on PTO 1449. Wensvoort et al. disclose nucleotide sequence of the genome of the Lelystad agent, which is a European strain of PRRSV (See, e.g., Figure 1). Wensvoort also discloses a diagnostic kit for detecting a PRRSV viral nucleic acid comprising nucleic acid probes or primers and suitable detection means as well as probes and primers to be used in diagnostic techniques such as hybridization and polymerase chain reaction for detecting specific nucleotide sequences (see, e.g., page 3, line 32-page 4, line 4; page 8, line 30-page 9, line 2; also claim 21). Wensvoort differs from the claimed invention only in not specifically disclosing specific primer length of 10-50 nucleotides that hybridize at a temperature of 25-75°C, and in not disclosing a fluorescent intercalating dye as the specific type of reagent for detecting amplified nucleic acid as recited in claim 31. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select primers that

hybridize to PRRSV sequences under more or less stringent conditions (i.e., at higher or lower temperatures) and that have appropriate lengths for use as primers and to use any conventional label for detecting hybridization, based on the disclosure of Wensvoort et al. that, once a viral genome sequence of interest is known (Fig. 1), one is motivated to select appropriately sized and constituted primers and to use conventional labels as is known in the art in order to specifically detect nucleotide acid sequences (page 8, line 30-page 9, line 2). Since the genomes of Iowa strain PRRSV and Lelystad virus share sequence identity over stretches of 10 nucleotides or more, and since the claims are rather unclear, primers of 10-50 nucleotides that hybridize to Iowa strain genome at 25-75°C or whose sequence is found in the genome of Iowa strain PRRSV are obvious over the disclosure of Wensvoort et al. of the Lelystad sequence and the suggestion to select appropriate primers for polymerase chain reaction, for example, and to use conventional detection means for detecting the nucleic acids that result.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
August 7, 2002